

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

In the specification, paragraph [0022] has been amended.

Claims 1 – 3, 13, 15, 19 and 21 are requested to be cancelled.

Claim 4 is currently amended.

Claims 23, 24 and 25 are added

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After entry of this response, claims 4 – 12, 14, 16 – 18, 20 and 22 – 25 are pending in this application.

**Objection to the Specification**

In item 2 of the Office Action, the Examiner has objected to the specification under 35 USC §112, first paragraph because the specification allegedly does not contain a written description of the invention in such a full, clear, concise, and exact terms as to enable any person skilled in the art to make and use the invention. In particular, the Examiner has required clarification vis-à-vis paragraph [0024] and the fact that this paragraph recites “20 mg of polymer.” The Examiner asserts that “it is not clear what, what is this polymer, since no polymer was mentioned earlier in the Example.”

Applicants point out that paragraph [0022], as amended to include the recitations of original claims 11 and 12, clearly states that the claimed method can be applied to the quantification of the monomer content in polymers, including possibly rare monomer components like cross-link sites and/or end groups. In short, the passage in paragraph [0024] that mentions a 20 mg polymer sample simply illustrates how the skilled artisan would use

the method described in paragraph [0022] to prepare and analyze a polymer sample. In this example, the polymer may be BPA polycarbonate. In light of this clarification, Applicants urge the Examiner to reconsider and withdraw the objection to the specification under 35 USC §112, first paragraph.

### **Objection to the Claims**

In item 3 of the Office Action, the Examiner has objected to claims 13 and 21, since a peptide allegedly can not be listed in the group of polymers. Without acquiescing to the Examiner's position, and simply in an effort to expedite the prosecution of this application, Applicants have cancelled claims 13 and 21. Reconsideration and withdrawal of this objection is therefore requested.

### **Claim Rejections Under 35 U.S.C. § 112, First Paragraph**

#### ***Item 5***

In item 5, it is Applicants' understanding that the Examiner rejects claims 1 – 10 and 14 – 16 under 35 U.S.C. § 112, first paragraph because claims 1 and 4 are broad enough to allegedly encompass inoperative embodiments. That is, the Examiner seems to take the position that claims 1 – 10 and 14 – 16 are not enabled for determining the relative concentrations of two or more components in a sample when the two or more components are distributed identically in the integral packets.

The Examiner is reminded that, according to MPEP § 2164.08(b), the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984) (prophetic examples do not make the disclosure nonenabling).

Applicants assert that the skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or have problems or would be

operative with expenditure of no more effort than is normally required in the art. In fact, Applicants assert that the skilled person would have to look no further than the specification, at paragraph [0015] to determine which embodiments would have problems. These include: (a) when two or more different components are distributed identically in the integral packets or (b) when the integral distribution of a component is a linear combination of the integral distribution of other components. In short, the Examiner has improperly rejected claims 1 – 10 and 14 – 16, because they are broad enough to cover certain inoperative embodiments. Reconsideration and withdrawal of these claims is respectfully urged.

In addition to the rejection under 35 U.S.C. § 112, first paragraph set forth at the beginning of item 5, the Examiner makes two conclusory statements for which she provides very little, if any, rationale.

The Examiner states that the specification is only enabling for NMR spectra for which signals are assigned at least to specific types of groups (e.g., methyl, methylene, methane, and quaternary carbon) for each mixture component. Further, the Examiner asserts that for <sup>13</sup>C spectra, the specification is only enabling for spectra obtained under special conditions and for mixture components of similar structure, since relaxation times determine the integral intensities of the signals. Applicants respectfully disagree with the Examiner's statements and assertions in light of the attached Declaration under 37 C.F.R. § 1.132 where the <sup>13</sup>C spectrum was obtained using general, standard conditions.

Although the Examiner cites the Mareci, Yamazaki, Alger and Laude references, it is not clear how those references support the aptness of the Examiner's statement.

Contrary to the Examiner's assessment, it is respectfully submitted that the present specification provides ample description that would allow the skilled artisan to make and use the invention in view of the present disclosure without undue experimentation. The Examiner is reminded that an enabling disclosure may require some experimentation, however, the issue is whether such experimentation is undue. *In re Angstadt*, 537 F.2d 498 (CCPA 1976).

Applicants assert that the Examiner has not met her burden in establishing a lack of enablement. Accordingly, reconsideration and withdrawal of the rejection based on 35 U.S.C. § 112, first paragraph are respectfully requested.

***Item 6***

In item 6 of the Office Action, the Examiner has rejected claims 12 – 13 and 20 – 21 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner asserts that the specification does not provide enablement for the method for determining the relative concentration of two or more components in a sample containing a mixture of polymers, especially proteins.

As an initial matter, Applicants have cancelled claims 13 and 19. Thus, the discussion that follows will focus only on claims 12, 17 and 20, which claims relate to a polymer or mixture of polymers and polymers comprising a soft segment BPA copolymer.

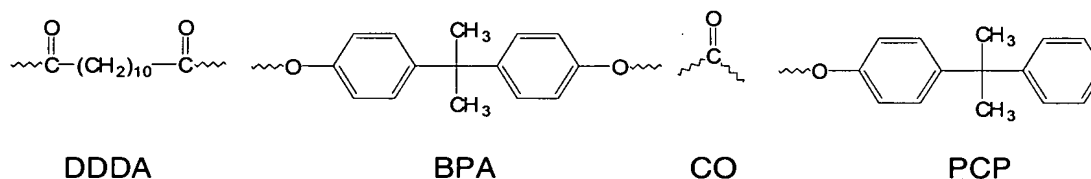
The Examiner once again seems to suggest that undue experimentation would be required to use the method claimed in claims 12 and 20 to determine the relative concentration of two or more components in a sample comprising a polymer or a mixture of polymers, where the polymer or mixture of polymers comprise a soft segment BPA polycarbonate. The Examiner has again failed to consider many of the other *In re Wands* factors that should be considered in evaluating whether a disclosure meets the enablement requirement. In particular, the Examiner has not considered, e.g., the level of one of ordinary skill in the art, the level of predictability in the art, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In short, the Examiner has not met her burden in establishing a lack of enablement.

Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 which demonstrates that no more than routine experimentation would be required to use the method claimed in claim 12, 17 and 20 to determine the relative concentration of two or more components in a sample comprising a soft segment BPA polycarbonate. Applicants assert that the method claimed in claims 12, 17 and 20 would also be easily applied, without undue experimentation, to samples where mixtures of polymers are analyzed.

Accordingly, reconsideration and withdrawal of the rejection based on 35 U.S.C. § 112, first paragraph are respectfully requested.

**Claim Rejections Under 35 U.S.C. § 112, Second Paragraph**

In item 8 the Examiner has rejected claims 11 – 13 and 17 – 21 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. The Examiner has asked for clarification vis-à-vis the two or more components that are present in the sample. Applicants offer that the two or more components to which claims 11 and 20 refer in the context of a polymer are the building blocks of the polymer or co-polymer. For example, in the Declaration submitted herewith, the two or more components are bisphenol A (BPA), dodecanedioic acid (DDDA), CO, and the end-capper, *para*-cumylphenol (PCP):



With the clarification given above, reconsideration and withdrawal of the rejection are respectfully requested.

**Claim Rejections Under 35 U.S.C. § 102(b)**

***Item 10***

In item 10, claims 1 – 2, 4 – 5, 7 – 10, and 14 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Warren *et al.* (*J. Pharm. Sci.* 1976). Applicants assert that Warren requires the use of an internal standard, viz., tetramethylammonium bromide, to determine the relative concentrations of a sample containing phenylglycine, dihydrophenylglycine, tetrahydrophenylglycine and cyclohexylglycine. In contrast, amended claim 4, by virtue of the closed language “consisting essentially of” excludes the use of an internal standard. Consequently, Warren does not anticipate claim 4. Claims 1 – 3 were cancelled and claim 17 was not rejected over Warren. Reconsideration and withdrawal of the rejection are respectfully requested.

***Item 11***

Claims 1 – 11, 14 and 17 – 18 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Landucci *et al.* (*Holzforschung*, 1998). It is axiomatic that, for a prior art reference to be anticipatory, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). Landucci does not seem to teach NMR quantitative spectroscopy for determining the relative concentration of two or more components in a sample as the Examiner suggests. Landucci certainly does not seem to teach the identification of resonance packets from a spectrum; integrating the resonance packets; identifying the number of nuclei that contribute to the integral data of the resonance packets; and determining the relative concentration of each component in the sample based on the integral data and on the number of nuclei. Thus, Applicants assert that Landucci does not disclose each and every element of the claimed invention, and the rejection should be withdrawn.

**Claim Rejections Under 35 U.S.C. § 103**

In item 14 the Examiner has rejected claims 15 – 16, 19 and 22 as allegedly being rendered obvious by Landucci (*supra*). This rejection has been rendered moot in light of the cancellation of claims 15, 16, 19 and 22. Reconsideration and withdrawal of this rejection are respectfully requested.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of

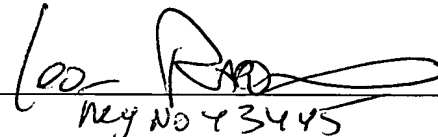
papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R.  
§1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date

4/25/04

By



~~For~~ Michael D. Kaminski  
Attorney for Applicants  
Registration No. 32,904

FOLEY & LARDNER LLP

Customer Number: 22428

Telephone: (202) 672-5490

Facsimile: (202) 672-5399